CLAIMS

The subject matter claimed is:

1. An injectable anesthetic composition comprising a microemulsion comprising a mixture of 2,6-diisopropylphenol, polyethylene glycol 660 hydroxystearate, tetrahydrofurfuryl alcohol polyethyleneglycol ether, and an aqueous medium.

2. The composition of claim 1 further comprising a surfactant selected from the group consisting of bile salts, lecithin, and mixtures thereof.

3. The composition of 2 wherein the composition comprises about 0.1 to 0.5% by weight of the surfactant.

4. The composition of claim 2 wherein the surfactant is a bile salt selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

5. The composition of claim 1 further comprising a bile salt.

6. The composition of claim 5 wherein the composition comprises about 0.1 to 0.5%

by weight of the bile salt.

7. The composition of claim 5 wherein the bile salt is a member selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

8. The composition of claim 1 further comprising lecithin.

9. The composition of claim 8 wherein the composition comprises about 0.1 to 0.5% by weight of the lecithin.

10. The composition of claim 1 further comprising a mixture of a bile salt and lecithin.

11. The composition of claim 10 wherein the composition comprises about 0.1 to 0.5% by weight of the mixture of a bile salt and lecithin.

12. The composition of claim 10 wherein the bile salt is a member selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid,

chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

13. The composition of claim 1 wherein the aqueous medium comprises a tonicity adjustment agent in an amount sufficient to obtain an isotonic condition corresponding to blood plasma.

14. The composition of claim 13 wherein the tonicity adjustment agent is a member selected from the group consisting of trehalose, glucose, fructose, glycerol, sorbitol, mannitol, sucrose, xylitol, sodium chloride, and mixtures thereof.

15. The composition of claim1 wherein the composition comprises about 1 to 2% by weight of 2,6-diisopropylphenol.

16. The composition of claim 1 wherein the composition comprises about 5 to 10% by weight of polyethylene glycol 660 hydroxystearate.

17. The composition of claim 1 wherein the composition comprises about 10 to 25% by weight of tetrahydrofurfuryl alcohol polyethyleneglycol ether.

18. The composition of claim 1 further comprising a member selected from the group consisting of liquid excipients, pH regulators, thickening agents, absorbents, light stabilizers, crystallization inhibitors, complexing agents, antioxidants, antiseptics, and mixtures thereof.

19. The composition of claim 18 wherein the composition comprises a liquid excipient selected from the group consisting of ethanol, propylene glycol, glycerol, triethylene glycol, polyethylene glycol, and mixtures thereof.

20. The composition of claim 18 wherein the composition comprises a pH regulator selected from the group consisting of citric acid, acetate, phosphoric acid, ascorbic acid, gluconic acid, succinic acid, tartaric acid, lactic acid, and salts thereof, and mixtures thereof.

21. The composition of claim 18 wherein the composition comprises a thickening agent selected from the group consisting of methylcellulose, hydroxyethyl cellulose, sodium carboxymethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, and mixtures thereof.

22. The composition of claim 18 wherein the composition comprises a complexing agent selected from the group consisting of EDTA and salts thereof, phosphate, nitrate, acetate, citrate, and mixtures thereof.

23. The composition of claim 18 wherein the composition comprises an antioxidant selected from the group consisting of ascorbic acid, sulfate compounds, L-cysteine,

thiodipropionic acid, thiolactic acid, monothioglycerol, propyl galate, and mixtures thereof.

24. The composition of claim 18 wherein the composition comprises an antiseptic selected from the group consisting of methyl *p*-oxybenzoate, propyl *p*-oxybenzoate, PHB ester, chlorobutanol, benzyl alcohol, butanol, butane-1,3-diol, chlorohexidin salts, benzoic acid and its salts, sorbic acid, and mixtures thereof.

25. The composition of claim 1 wherein the composition exhibits a transmittance at 660 nm of greater than about 90%.

26. A method of making an injectable anesthetic composition comprising:

(a) mixing polyethylene glycol 660 hydroxystearate with an aqueous medium to result in an aqueous mixture and heating and then cooling the aqueous mixture to room temperature to result in an aqueous solution;

(b) adding 2,6-diisopropylphenol to tetrahydrofurfuryl alcohol polyethyleneglycol ether to result in an oil-phase mixture and heating and then cooling the oil-phase mixture to room temperature to result in an oil-phase solution;

(c) mixing the aqueous solution and the oil-phase solution with stirring to result in a stirred mixture; and

(d) heating the stirred mixture with additional stirring and then cooling to room temperature to result in a microemulsion, thereby resulting in the injectable anesthetic composition.

27. The method of claim 26 wherein the aqueous medium comprises a tonicity adjustment agent selected from the group consisting of trehalose, glucose, fructose, glycerol, sorbitol, mannitol, sucrose, xylitol, sodium chloride, and mixtures thereof.

28. The method of claim 26 wherein the aqueous medium comprises a surfactant selected from the group consisting of bile salts, lecithin, and mixtures thereof.

29. The method of claim 28 wherein the surfactant is a bile salt selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

30. The method of claim 26 wherein the aqueous medium comprises a pH regulator selected from the group consisting of citric acid, acetate, phosphoric acid, ascorbic acid, gluconic acid, succinic acid, tartaric acid, lactic acid, and salts thereof, and mixtures thereof.

31. The method of claim 26 wherein the aqueous medium comprises a thickening agent selected from the group consisting of methylcellulose, hydroxyethyl cellulose, sodium carboxymethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, and mixtures thereof.

32. The method of claim 26 wherein the aqueous medium comprises a complexing agent selected from the group consisting of EDTA and salts thereof, phosphate, nitrate, acetate, citrate, and mixtures thereof.

33. The method of claim 26 wherein the aqueous medium comprises an antioxidant selected from the group consisting of ascorbic acid, sulfate compounds, L-cysteine, thiodipropionic acid, thiolactic acid, monothioglycerol, propyl galate, and mixtures thereof.

34. The method of claim 26 wherein the aqueous medium comprises an antiseptic selected from the group consisting of methyl *p*-oxybenzoate, propyl *p*-oxybenzoate, PHB ester, chlorobutanol, benzyl alcohol, butanol, butane-1,3-diol, chlorohexidin salts, benzoic acid and its salts, sorbic acid, and mixtures thereof.

35. The method of claim 26 wherein heating of the aqueous mixture, the oil-phase mixture, and the stirred mixture is carried out at 40-80°C.

36. A method for anesthetizing an animal or human comprising injecting the animal or human with an amount of an anesthetic composition effective for inducing or maintaining anesthesia, wherein the composition comprises a microemulsion comprising a mixture of 2,6-diisopropylphenol, polyethylene glycol 660 hydroxystearate, tetrahydrofurfuryl alcohol polyethyleneglycol ether, and an aqueous medium.

37. The method of claim 36 wherein the composition further comprises a surfactant selected from the group consisting of bile salts, lecithin, and mixtures thereof.

38. The method of 37 wherein the composition comprises about 0.1 to 0.5% by weight of the surfactant.

39. The method of claim 37 wherein the surfactant is a bile salt selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

40. The method of claim 36 wherein the composition further comprises a bile salt.

41. The method of claim 40 wherein the composition comprises about 0.1 to 0.5% by weight of the bile salt.

42. The method of claim 40 wherein the bile salt is a member selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid,

glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

43. The method of claim 36 wherein the composition further comprises lecithin.

44. The method of claim 43 wherein the composition comprises about 0.1 to 0.5% by weight of the lecithin.

45. The method of claim 36 wherein the composition further comprises a mixture of a bile salt and lecithin.

46. The method of claim 45 wherein the composition comprises about 0.1 to 0.5% by weight of the mixture of a bile salt and lecithin.

47. The method of claim 45 wherein the bile salt is a member selected from the group consisting of pharmaceutically acceptable salts of cholic acid, deoxycholic acid, chenodeoxycholic acid, lithocholic acid, ursocholic acid, ursodeoxycholic acid, isoursodeoxycholic acid, lagodeoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, dehydrocholic acid, hyocholic acid, hyodeoxycholic acid, and mixtures thereof.

48. The method of claim 36 wherein the aqueous medium comprises a tonicity

adjustment agent in an amount sufficient to obtain an isotonic condition corresponding to blood plasma.

49. The method of claim 48 wherein the tonicity adjustment agent is a member selected from the group consisting of trehalose, glucose, fructose, glycerol, sorbitol, mannitol, sucrose, xylitol, sodium chloride, and mixtures thereof.

50. The method of claim 36 wherein the composition comprises about 1 to 2% by weight of 2,6-diisopropylphenol.

51. The method of claim 36 wherein the composition comprises about 5 to 10% by weight of polyethylene glycol 660 hydroxystearate.

52. The method of claim 36 wherein the composition comprises about 10 to 25% by weight of tetrahydrofurfuryl alcohol polyethyleneglycol ether.

53. The method of claim 36 further comprising a member selected from the group consisting of liquid excipients, pH regulators, thickening agents, absorbents, light stabilizers, crystallization inhibitors, complexing agents, antioxidants, antiseptics, and mixtures thereof.

54. The method of claim 53 wherein the composition comprises a liquid excipient selected from the group consisting of ethanol, propylene glycol, glycerol, triethylene glycol,

polyethylene glycol, and mixtures thereof.

55. The method of claim 53 wherein the composition comprises a pH regulator selected from the group consisting of citric acid, acetate, phosphoric acid, ascorbic acid, gluconic acid, succinic acid, tartaric acid, lactic acid, and salts thereof, and mixtures thereof.

56. The method of claim 53 wherein the composition comprises a thickening agent selected from the group consisting of methylcellulose, hydroxyethyl cellulose, sodium carboxymethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, and mixtures thereof.

57. The method of claim 53 wherein the composition comprises a complexing agent selected from the group consisting of EDTA and salts thereof, phosphate, nitrate, acetate, citrate, and mixtures thereof.

58. The method of claim 53 wherein the composition comprises an antioxidant selected from the group consisting of ascorbic acid, sulfate compounds, L-cysteine, thiodipropionic acid, thiolactic acid, monothioglycerol, propyl galate, and mixtures thereof.

59. The method of claim 53 wherein the composition comprises an antiseptic selected from the group consisting of methyl *p*-oxybenzoate, propyl *p*-oxybenzoate, PHB ester, chlorobutanol, benzyl alcohol, butanol, butane-1,3-diol, chlorohexidin salts, benzoic acid and its salts, sorbic acid, and mixtures thereof.

60. The method of claim 36 wherein the composition exhibits a transmittance at 660 nm of greater than about 90%.